UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,657	05/25/2000	Misako Mizuno	029430-454	6902

21839 7590 09/16/2002

BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER
KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 09/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/577,657	Applicant(s) MIZUNO ET AL.	
	Examiner Anne R. Kubelik	Art Unit 1638	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☒ Applicant's reply has overcome the following rejection(s): *See Continuation Sheet*.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-7, 13-14, 16-17, 20-23 and 27-28*.

   Claim(s) withdrawn from consideration: *8-10, 15 and 24-26*.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *See Continuation Sheet*

Continuation of 2. NOTE:
New issues: Claims 1(b) and 4(b) lack antecedent basis for the limitation "said modified nucleic sequence".

Continuation of 3. Applicant's reply would have overcome the following rejection(s):
The objections to claims 1, 4, 14, 17, 20-21 and 27.

Continuation of 5. does NOT place the application in condition for allowance because:
112, 1st, enablement: As stated of record, without guidance in the specification as to which amino acids are critical for protein function, an undue number of nucleic acids would need to be made and analyzed. The specifiction on the pages cited by Applicant does not state the SPECIFIC hybridization conditons needed to isolate modified nucleic acids, but gives vast ranges - Applicant has not isolated nucleic acids using any of these ranges. See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at pg 1027:
"... despite extensive statements in the specification concerning all the analogs of the EPO gene that can be made, there is little enabling disclosure of particular analogs and how to make them. Details for preparing only a few EPO analog genes are disclosed. Amgen argues that this is sufficient to support its claims; we disagree. This 'disclosure' might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for Amgen's desire to claim all EPO gene analogs. There may be many other genetic sequences that code for EPO-Type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them."
The experiment on pg 36-37 transformed E. coli with SEQ ID NO:2, which encodes a 13 amino acid longer protein than SEQ ID NO:2 - a protein that starts with Met. No cells were transformed with a nucleic acid that encodes only SEQ ID NO:1 (which does not start with a Met) to show that such a nucleic acid encodes a protein with the listed activites, as stated in the prior Office actions.
While Applicant is enabled for antisense suppression of coffee with SEQ ID NO:2, it is not enabled for antisense suppression of other plants with SEQ ID NO:2 or of any plant with any nucleic acid that hybridizes to any nucleic acid that encodes SEQ ID NO:1, as stated in the prior Office actions; see also Colliver et al, cited in the Office action of 16 October, 2001, which discusses the unpredictability of antisense suppression with nucleic acids that are not 100% identical to the target nucleic acid. Applicant is again invited to submit a Declaration that demonstrates that the levels of caffeine in another plant were altered by transformation with SEQ ID NO:2 or any nucleic acid that hybridizes to a nucleic acid that encodes SEQ ID NO:1.
Amendment of claim 20 to limit the plant secondary metabolites to 7-methyl xanthine, paranthine, theobromin and caffeine is appreciated.

112, 1st, written description: Applicant is claiming more than the genus of nuclaic acids encoding SEQ ID NO:1 - if the claims were limited to nucleic acids encoding SEQ ID NO:1, this rejection would be withdrawn. However, Applicant is claiming nucleic acids that hybridize to nucleic acids encoding SEQ ID NO:1 under unspecified hybridization conditions and the specification does not describe the structural features of all these nucleic acids.

112, 2nd: It remains unclear in claims 1(b) and 4(b) what it means to "maintain" an enzyme activity.
Claims 2 and 5 remain indefinite because salt concentrations are not recited.
In claims 2 and 5, line 2, "and" should be replaced with --or--.

Continuation of 10. Other: With respect to the substitute specification: no clean copy of the substitute specification was incldued in the response; only a marked-up copy was present. Thus, a substitute copy could not be entered.

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638